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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,145	05/05/2005	Charles Reay MacKay	RICE-032	8992

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
03/01/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,145	MACKAY, CHARLES REAY	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/14/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,15,20 and 25-60* is/are pending in the application.

4a) Of the above claim(s) *40-51* is/are withdrawn from consideration.

5)☒ Claim(s) *29-32 and 52-60* is/are allowed.

6)☒ Claim(s) *1-10, 15, 20, 25-28, 33--39,* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 12/14/2010, has been entered

Claims 10, 15, 20 and 52-54 have been amended.

Claims 55-60 have been added.

Claims 11-14, 16-19 and 21-24 have been canceled previously.

Claims 1-10, 15, 20 and 25-60 are pending.

Claims 1-10, 15, 20, 25-39 and 52-60 are under consideration in the instant application as they read on the elected invention.

Claims 40-51 have been withdrawn from consideration as they read on non-elected inventions/species.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Office Action will be in response to applicant's arguments, filed 12/14/2010.

The rejections of record can be found in the previous Office Action, mailed 09/14/2010.

3. Applicant's submission /amendments, filed 12/14/2010, have placed this application in compliance with the Sequence Rules.

4. Priority.

As noted previously, the effective filing date of the instant claims is deemed to be the filing date of the priority application PCT/AU03/00084, filed 01/24/2003, as the previous priority application USSN 60.350,961 does not support the claimed limitations of the instant application, encompassing antibodies that are reactive with the extracellular loop of C5aR other than the N-terminal domain, including the second extracellular loop of C5aR and antibodies, 6C12 and 12D4.

For example, the written description of USSN 60/350,961 appears limited to the 7F3 anti-C5aR antibody only in the context of the instant claimed invention.

Applicant's amendment, filed 12/14/2010, does not appear to disagree with this analysis of priority.

5. This is a rejection under 35 USC § 112, first paragraph, "written description" (and not new matter).

Claims 10, 15 and 20 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

Applicant's arguments in conjunction with the Written Description Guidelines and MPEP 2163, filed 12/14/2010, have been fully considered but have not been found convincing essentially for the reasons of record as it applies to the amended recitation of "at least 95% amino acid sequence identity to the amino acid sequences of heavy and light chains" of the claimed antibodies.

In addition to reliance upon the Written Description Guidelines and MPEP 2163, applicant argues that the specification provides adequate written description as to the specificity of the antibody and as how to determine information as to the specificity and activity of the claimed antibodies.

In contrast to applicant's arguments and as noted previously, the problem here is that the instant specification fails to provide a disclosure of which residues are required for the claimed anti-C5aR antibodies to be substantially the same and retain the appropriate antibody specificity for C5aR. A skilled artisan cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus that exhibit this functional property.

Therefore, there is insufficient written description for genera of "at least 95% amino acid sequence identity to the amino acid sequences of heavy and light chains" of the claimed antibodies, broadly encompassed by the claimed invention, other than the specific heavy and light chain sequences of the 7F3, 6C12 and 12D4 antibodies described in the specification and claimed under the written description provision of 35 USC 112, first paragraph.

The following is reiterated for applicant's convenience as it applies to "at least 95% amino acid sequence identity".

There is insufficient written description encompassing "comprising at least 95% amino acid sequence identity to the amino acid sequences ... " as it reads on antibodies reactive with C5aR of the claimed invention because the relevant identifying characteristics such as structure of other physical and/or chemical characteristics of "anti-C5aR antibody" are not set forth in the specification as-filed, commensurate in scope with the claimed invention.

For example, given the well known high level of polymorphism of immunoglobulins / antibodies, the skilled artisan would not have been in possession of the vast repertoire of antibodies and the unlimited number of antibodies encompassed by the claimed invention;

one of skill in the art would conclude that applicant was not in possession of the structural attributes of a representative number of species possessed by the members of the genera of "95% sequence identical light and heavy chain sequences" of the claimed antibodies and /or antigens as indicated above, and broadly encompassed by the claimed invention.

One of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genera.

It has been well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity, which is characteristic of the parent immunoglobulin. All of the heavy and light chain CDRs should be in their proper order and in the context of framework sequences which maintain their required conformation in order to provide a binding molecule having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites.

Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al (Proc Natl Acad Sci USA 79: 1979-1983 (1982) (892; of record).

Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function.

Single amino changes to either a CDR or even in certain circumstances to the framework can result in decrease affinity of antigen or even ablation of antibody binding and specificity.

Also, see the teachings of Colman (Research in Immunology 145: 33-36, 1994) on the effects of amino acid sequence changes on antibody-antigen interactions.

In addition, Kussie et al. (J. Immunol. 152: 146-152, 1994) (e.g., see entire document, including Table I) teach that the substitution of a single amino acid can totally ablate antigen binding.

Further, Chen et al. (EMBO J., 14: 2784-2794, 1995) teach that the substitution of a single amino acid can totally ablate antigen and that the same substitution in closely related antibodies can have opposite effects binding (e.g., see entire document, including Figure I). For example, the authors compared the effects of identical substitutions in related antibodies DI6 and TI5, and as shown in Figure 3, some substitutions increased antigen binding in one antibody while ablating it in the other.

The disclosure fails to describe the common attributes or characteristics that identify members of the genera of "at least 95% amino acid sequence identity to the amino acid sequences of heavy and light chains" of the claimed antibodies.

While the instant specification does disclose screening for homologous heavy and light chain of the claimed antibodies (e.g., see pages 18-21 of the specification),

the instant application has not provided a sufficient description showing possession of the necessary functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genera of "at least 80% amino acid sequence identity to the amino acid sequences of heavy and light chains" of the claimed antibodies, broadly encompassed by the claimed invention.

Further, the Court has interpreted 35 U.S.C. §112, first paragraph, to require the patent specification to "describe the claimed invention so that one skilled in the art can recognize what is claimed. Enzo Biochem, Inc. v. Gen-Probe Inc, 63 USPQ2d 1609 and 1618 (Fed. Cir. 2002). In evaluating whether a patentee has fulfilled this requirement, our standard is that the patent's "disclosure must allow one skilled in the art 'to visualize or recognize the identity of' the subject matter purportedly described." Id. (quoting Regents of Univ. of Cal. v. Eli Lilly & Co., 43 USPQ2d 1398 (Fed Cir. 1997)).

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483.

The Court has held that the disclosure of screening assays and general classes of compounds was not adequate to describe compounds having the desired activity: without disclosure of which peptides, polynucleotides, or small organic molecules have the desired characteristic, the claims failed to meet the description requirement of § 112. See University of Rochester v. G.D. Searle & Co., Inc., 69 USPQ2d 1886,1895 (Fed. Cir. 2004).

The problem here is that the instant specification fails to provide a disclosure of which residues are required for the claimed anti-C5aR antibodies to be substantially the same and retain the appropriate antibody specificity for C5aR. A skilled artisan cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus that exhibit this functional property.

Therefore, there is insufficient written description for genera of "at least 95% amino acid sequence identity to the amino acid sequences of heavy and light chains" of the claimed antibodies, broadly encompassed by the claimed invention, other than the specific heavy and light chain sequences of the 7F3, 6C12 and 12D4 antibodies described in the specification and claimed under the written description provision of 35 USC 112, first paragraph.

Applicant's arguments have not been found persuasive.

Applicant is invited to amend the claims to avoid the recitation of "95% identical … " to avoid this rejection.

Applicant is been reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

6. Claims 5, 8, 29 and 32 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Applicant's remarks, filed 12/14/2010, concerning the appropriate claims corresponding to 12D4 (ECACC accession number 02090227) and the recitation of "04090801" is acknowledged.

In turn, given the recitation of "04090801", the appropriate claims associated with this rejection are claims 5, 8, 29 and 32.

Applicant's provision of the appropriate assurances for the deposit of biological material is acknowledged.

However, the following of record is noted.

Given applicant's Remarks, filed 11/02/2009, as indicated herein,
the following rejection under 35 U.S.C. § 112, first paragraph, enablement for the deposit of biological materials is set forth.

The specification is also amended to reflect a new deposit made with the ECACC. Since filing this application, it has come to light that the microorganism sample deposited with ECACC as 12D4 (ECACC accession number 02090227) was not the correct sample. A new deposit of the 12D4 antibody hybridoma was made at ECACC on September 8, 2004. The new deposit name is 12D4-N17 and the accession number is 04090801. The sequence listing information provided in the specification as filed for 12D4 is correct. Under current law, a microorganism deposit must be made before issue of the patent but not necessarily prior to the filing date. Accordingly, the Applicants would now like to amend the specification to reflect the correct deposit details for 12D4, which is now designated 12D4-N17.

It is apparent that the 12D4 antibody / hybridoma is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In the absence of a statement from a person in a position to corroborate the fact and stating that the replaced or supplement deposit is of a biological which is identical to the originally deposited or described in the specification,
the deposit of 12D4-N17 is not sufficient for satisfying the requirements under 35 U.S.C. § 112, first paragraph, enablement for the deposit of biological materials for the originally disclosed 12D4 antibody described in the specification as-filed.
See MPEP 2406.02 and 2407.

Applicant's arguments have not been found persuasive.

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7. This is a rejection under 35 USC § 112, first paragraph, written description / new matter.

Claims 5, 8, 29 and 32 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed: "accession number 04090801".

Applicant's remarks, filed 12/14/2010, concerning the appropriate claims corresponding to 12D4 (ECACC accession number 02090227) and the recitation of "04090801" is acknowledged.

In turn, given the recitation of "04090801", the appropriate claims associated with this rejection are claims 5, 8, 29 and 32.

Applicant's provision of the appropriate assurances for the deposit of biological material is acknowledged.

However, the following of record is noted.

For the reasons set forth above in Section 6,

in the absence of a statement from a person in a position to corroborate the fact and stating that the replaced or supplement deposit is of a biological which is identical to the originally deposited or described in the specification,

the deposit of 12D4-N17 is not sufficient for satisfying the requirements under 35 U.S.C. § 112, first paragraph, enablement for the deposit of biological materials for the originally disclosed 12D4 antibody described in the specification as-filed

In turn, the recitation of accession number 04090801 in the context of 12D4-N17 is deemed new matter to the instant application as-filed.

The specification does not provide sufficient blazemarks nor direction for the instant recitation of accession number 04090801 in the context of 12D4-N17, as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

However, if applicant provides for a statement from a person in a position to corroborate the fact and stating that the replaced or supplement deposit is of a biological which is identical to the originally deposited or described in the specification as 12D4,

then this rejection may be obviated.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above.
See MPEP 714.02 and 2163.06

Applicant's arguments have not been found persuasive.

8. Specification: The amendment filed 11/02/2009, is objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure.

Please replace the paragraph starting line 10 on page 12, with the following:

The hybridoma which produces the monoclonal antibody designated 12D4 (12D4-N17) was deposited on ~~2 September 2002~~ September 8, 2004 with ECACC under accession number ~~02090227~~ 04090801 (European Collection of Cell Cultures (ECACC), Porton Down, Salisbury, Wiltshire, SP4 0JG, United Kingdom).

35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention.

The added material which is not supported by the original disclosure is as follows: "(12D4-N17) was deposited on September 8, 2004 with ECACC under accession number 04090801".

However, if applicant provides for a statement from a person in a position to corroborate the fact and stating that the replaced or supplement deposit is of a biological which is identical to the originally deposited or described in the specification as 12D4,
then this objection may be obviated.

If not, then applicant is required to cancel the new matter in the reply to this Office Action.

As noted above, applicant's remarks, filed 12/14/2010, concerning reliance upon the assurances alone is not sufficient for above-mentioned amendment to the specification corresponding to 12D4 (ECACC accession number 02090227) and the recitation of "04090801".

Applicant's arguments have not been found persuasive.

9. Claims 1-9, 25-28 and 33-39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Morgan et al. (U.S. Patent No. 5,480,974) (892; of record) in view of Cain et al. (Biochemical Pharmacology 61: 1571-1579, 2001) (1449; #2), Crass et al. (J. Biol. Chem 274: 8367-8370, 1999), Oppermann et al. (J. Immunol. 151: 3785-3794, 1993) (1449) and Pease et al. (Eur. J. Immunol 24: 211-215, 1994).

Applicant's arguments, filed 12/14/2010, have been fully considered but have not been found convincing essentially for the reasons of record.

The strongest rationale for combining reference is a recognition, expressly or implicitly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent that some advantage or expected beneficial result would have been produced by their combination. In re Sernaker 17 USPQ 1, 5-6 (Fed. Cir. 1983). See MPEP 2144.

One cannot show non-obviousness by merely asserting that the references do not provide the sufficient elements of obviousness or by attacking references individually where the rejections are based on a combination of references. In re Young, 150 USPQ 725 (CCPA 1968).

For example, with respect to the applicant's remarks concerning the deficiencies of Morgan et al., it is the combination of references that supports the obviousness rejection.

While applicant notes that Oppermann et al. teach that only antibodies specific for the receptor's amino domain inhibited C5a binding,
Oppenheim was provided for the identification of the C5a receptor binding sites of the C5a receptor, including information describing extracellular loops other than the N-terminal domain (see entire documents, including Introductions, Materials and Methods, Results and Discussion).

While it is acknowledged that Oppermann et al. teach that only antibodies specific for the receptor's amino domain inhibited C5a binding,
the obviousness rejection is based upon the combination of references, including the teachings of Pease et al., Cain et al. and Crass et al.

While applicant acknowledges that Pease et al. teach that the N-terminus and the second and third extracellular loops may be involved in C5a binding,
Pease et al. provides alternative explanations as well.

Further, applicant asserts that Pease et al. does not conclusively non-N-terminal loops as being involved in C5a binding

While it is acknowledged that Pease et al. note that the role of the amino terminus and extracellular loops two and three cannot be sufficient to interrupt the interaction of receptor and ligand (see Concluding Remarks on page 214),
Pease et al. does clearly direct the ordinary artisan to targeting the second and third extracellular loops of the C5a receptor in the formation of the binding site for C5a (e.g., see page 214, column 2, paragraph 1).

In a followup to this 1994 publication and in contrast to applicant's assertions that Crass et al. supports the notion that the N-terminus is the most important ligand binding site for C5a receptors and C5a, but provides no compelling reason to target the second loop,
the 1999 Crass et al. publicaiton does teach that the second extracellular loop is critically involved in the two-site model for the human C5a receptor (see entire document, including Abstract, Results and Discussion; including page 8370, EL2 Influences Correct Positioning of the Transmembrane Helix Bundle).

While applicant notes that Cain et al. relies upon the teachings of Pease et al. (addressed above) and cannot distinguish between the role of residues in the first loop and mutations changing conformations and
while applicant notes that Cain et al. points out the variations in C5aR binding sites among peptide and agonists and antagonists;
the 2001 Cain et al. et al. publication clearly states that the two of the extracellular loops, (namely the second and third) and the N-terminal domain are essential for C5a binding (e.g., see page 1572, column 1, paragraph 1).

It is noted that the claims do not specify any level of reducing or inhibiting the binding of C5a to C5aR, thus the claims read on any measurable reduction or inhibition of binding between C5a and C5aR via antibodies that binding to an extracellular loop of C5aR other than the N-terminal domain.

Giving the claims the broadest reasonable interpretation, see In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) and the combination of references concerning the role of two of the extracellular loops (namely the second and third) and the N-terminal domain as being essential for C5a binding,
One of ordinary skill in the art would have been motivated to make and use antibodies that target the second and third extracellular loops of C5aR in order to inhibit C5a binding to C5aR with an expectation of success.

Note that references subsequent to the 1993 Oppermann et al. publication support the role of two of the extracellular loops (namely the second and third) as well as the N-terminal domain in C5a binding to C5aR at the time the invention was made, as addressed herein and of record.

The following is reiterated for applicant's convenience.

Morgan et al. teach making and using C5a receptor (C5aR) -specific antibodies, including antagonistic antibodies, conjugates and compositions thereof (see entire document, including Summary of the Invention, Detailed Description of the Invention, particularly columns 2-12 and Examples and Claims).

Morgan et al. differs from the claimed invention by not describing antibodies, including antagonistic antibodies that necessarily target an extracellular loop other than the N-terminal domain or the second extracellular loop, including the 7F3, 6C12 and 12D4 antibody specificities.

Studies of chimeric C5a receptors have indicated the role of the second extracellular loop in C5a binding as follows.

While Cain et al. focuses on the modulation of ligand selectivity by mutation of the first extracellular loop of the human C5a receptor,
Cain et al. et al. also teaches that two of the extracellular loops, namely the second and third) and the N-terminal domain are essential for C5a binding (e.g., see page 1572, column 1, paragraph 1).

Crass et al. teach that the second extracellular loop is critically involved in the two-site model for the human C5a receptor (see entire document, including Abstract, Results and Discussion; including page 8370, EL2 Influences Correct Positioning of the Transmembrane Helix Bundle).

Consistent with the teachings herein (e.g., Cain et al. cites Pease et al. as reference 13 and Crass cites Pease et al. as reference 10;
both Oppenheim et al. and Pease et al. provide for the identification of the C5a receptor binding sites of the C5a receptor, including information describing extracellular loops other than the N-terminal domain (see entire documents, including Introductions, Materials and Methods, Results and Discussion).

Given the limited number of epitopes on the second extracellular loop of the C5a receptor, antagonistic antibodies directed toward the second extracellular loop of the C5a receptor would have been expected to compete or bind to the same epitope as the claimed 7F3, 6C12 and 12D4 antibodies.

The Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons. The burden is on the applicant to establish a patentable distinction between the antagonistic antibodies that bind second extracellular loop of the C5a receptor and the epitope specificity of the claimed 7F3, 6C12 and 12D4 antibodies.

Given the teachings of making and using antagonistic C5a receptor-specific antibodies as well as the teachings of modulation via C5a receptor antagonists by Cain et al.,
one of ordinary skill in the art at the time the invention was made would have been motivated to target the second extracellular loop with C5a receptor-specific antibodies to determine structure-function relationship of this structure to C5a Receptor-mediated biological activities as well as to generate detection, diagnostic and therapeutic tools for a variety of utilities as taught by Morgan et al. (e.g., see columns 9-12).

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Applicant arguments have not been found persuasive.

10. Due to high polymorphism of antibodies, the claimed 7F3, 6C12 and 12D4 C5a receptor-specific antibodies are deemed structurally distinct on the primary amino acid basis. These particular C5a receptor-specific antibodies do not appear to known or taught in the prior art. The prior art neither suggest or teaches C5a receptor antibodies having the exact chemical structure as these particular antibodies.

Claims 29-32 and 52-60 are deemed allowable.

As noted above, antibodies competing or binding the same epitopes as these particular 7F3, 6C12 and 12D4 C5a receptor-specific antibodies were obvious to one of ordinary skill in the art at the time the invention was made.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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